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PATENT  
Docket No.: 56466US002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

KRISTIN J. GODBEY, STEVEN S.  
KANTNER and MATTHEW T. SCHOLZ

Serial No.: 09/854,824  
Filed: May 14, 2001

For: SYSTEM FOR DELIVERING  
COSMETICS AND  
PHARMACEUTICALS

Group Art Unit: 1615


Examiner: S. Howard

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on:

January 6, 2004

Date

  
Signature Judy L. Hansen

BRIEF ON APPEAL

Mail Stop Appeal Briefs-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

This Brief on Appeal is being submitted in response to a Final Rejection dated July 2, 2003. This Brief is being filed in triplicate. The fee of \$330.00 under 37 CFR 1.17(c) for the appeal should be charged to Deposit Account No. 13-3723. Appellants also request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

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REAL PARTY IN INTEREST

The real party in interest is 3M Company (formerly known as Minnesota Mining and Manufacturing Company) of St. Paul, Minnesota and its affiliate 3M Innovative Properties Company of St. Paul, Minnesota.

### **RELATED APPEALS AND INTERFERENCES**

Applicants are unaware of any other pending U.S. Patent Applications which are on appeal and which have issues that overlap with any issue in this Appeal. Applicants are also unaware of any Interference proceeding before the U.S. Patent and Trademark Office that has any substantive relationship to the subject matter of this Appeal.

### **STATUS OF CLAIMS**

Claims 1-39 are pending in the application. Claims 40-50 are withdrawn from consideration and have been canceled based on a restriction requirement under 35 U.S.C. 121. Claims 1-39 stand finally rejected under 35 U.S.C. § 103(a) and are being appealed.

### **STATUS OF AMENDMENTS**

Claims 1-39 stand as amended by Applicants' Response and Amendment submitted on October 2, 2003. Applicants timely filed a Notice of Appeal following a final Office Action mailed July 2, 2003.

### **SUMMARY OF THE INVENTION**

The present invention relates generally to a device for delivery of an active agent that may be designed to have properties advantageous for delivery of a large number and variety of active agents. Generally, the device of the present invention may be designed to be easy to apply and easy to remove. In some embodiments, the device may be designed to deliver a pre-measured unit dose of agent to a limited, specific area. Certain embodiments of the device may be applied to dry skin, hair or nails while other embodiments of the device may be applied to moistened surfaces such as teeth or mucous tissue. The device of the present invention may be designed variously for providing prolonged treatments or for dissolving or dispersing rapidly in water.

The device includes a substantially water-soluble or substantially water-dispersible carrier for the delivery of one or more active agents. The carrier may be a

film, fabric, tape, or any other form suitable for delivery of the active agent. The device also includes a substantially water-soluble or substantially water-dispersible adhesive disposed on at least a portion of one surface of the carrier. The active agent may include one or more pharmaceutical, cosmetic, decorative or other suitable type of agent. The active agent may be coated onto, dissolved into, suspended in, emulsified with, or otherwise applied to the carrier, the adhesive, or both. The device optionally includes one or more support layers releasably adhered to the carrier, the adhesive or both. Consequently, as used herein, "device" refers to the combination of a carrier, the adhesive and at least one active agent, either with or without a support layer.

### **ISSUES ON APPEAL**

1. Whether claims 1-39 are patentable under 35 U.S.C. § 103(a) over the disclosure of U.S. Pat. No. 5,688,523 ("Garbe") in view of U.S. Patent No. 6,019,997 ("Scholz").

### **GROUPING OF CLAIMS**

With regard to the various rejections of the pending and appealed claims, Applicants believe claims 1-14 and 15-39 stand or fall together.

### **ARGUMENTS OF APPELLANTS**

#### **Patentability of Claims 1-39 under 35 U.S.C. § 103(a)**

Claims 1-39 stand rejected by the Examiner under 35 U.S.C. § 103(a) over U.S. Pat. No. 5,688,523 ("Garbe") in view of U.S. Patent No. 6,019,997 ("Scholz"). The Examiner states that Garbe teaches an adhesive sheet material composed of "a water-soluble carrier comprising addition polymers (e.g. acrylates)," liquid excipients "which can read on plasticizers," and "a backing film."

Applicants respectfully disagree with the position set forth in the Office Action. The combination of references cited in the Office Action fails to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met:

- 1) there must be some suggestion or motivation, either in the reference or the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings;
- 2) there must be a reasonable expectation of success;
- 3) the prior art reference, or combined references must teach or suggest all the claim limitations.

*See Karsten Manufacturing Corp. v. Cleveland Golf Co.*, 242 F. 3d 1376, 58 USPQ2d 1286 (Fed. Cir. 2001); MPEP § 706.02(j).

Garbe and the patents Garbe incorporates by reference, are concerned with transdermal delivery devices that provide pervasive adhesion on skin without excessive residue or adhesion loss (col. 1, lines 15-23; col. 5, lines 36-62). The patent does not teach or suggest a combination of layers, each layer capable of dissolving or dispersing once in contact with water.<sup>1</sup> In contrast to the Office Action's characterization of the reference, Garbe lacks any discussion of the water-solubility of the polymer layers or the pressure sensitive sheet formed after constructing the layers together.

The Office Action fails to point out any teaching in Garbe to water-solubility of the polymers, or the pressure sensitive adhesive as disclosed therein. Garbe discloses neither the water-soluble / water-dispersible carrier nor the water-soluble / water-dispersible adhesive of the present invention. Rather, Garbe teaches a method of manufacturing a pressure sensitive adhesive sheet with layers that lack the characteristics of the present invention, namely water-solubility or water-dispersibility.

In specifying the polymers for use in Garbe's disclosure, Garbe incorporates by reference the polymers listed in U.S. Patent No. 4,732,808 to Krampe (column 9, lines 50-57) and silicone polymers listed in U.S. Patent No. 5,232,702 to Pfister. The polymers listed in Krampe and Pfister are water-insoluble. Further, suitable backing layers listed in Garbe (column 3, lines 30-40) are also water insoluble. Applicants maintain that Garbe fails to teach that any layer is composed of water soluble/water dispersible material.

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<sup>1</sup> For purposes of analysis, Garbe's "addition polymers" with the "liquid excipient" diffused in the polymer can be considered equivalent in structure to Applicants' adhesive layer. Garbe's "backing film" can be considered equivalent in structure to Applicants' carrier layer. Garbe's optional release liners and differential release liners are equivalent in structure to Applicants' support layer or carrier layer.

Even assuming for purposes of argument that Garbe taught water soluble polymers in the adhesive layer, which Applicants' dispute, Garbe fails to teach a water-soluble backing film. None of the conventional flexible backing materials listed in col. 3, lines 31-40 can be considered remotely water soluble. Further, Garbe makes no mention of including plasticizer in the backing film. Thus, even under the interpretation of Garbe put forth by the Examiner, Garbe would teach only one water-soluble layer (again which Applicants' dispute). In contrast, Applicants require that both layers, namely the adhesive layer and the carrier layer, be substantially water-soluble/water dispersible, as recited in independent claims 1 and 15.

In contrast, Garbe lacks any discussion of water solubility at all. Rather, Garbe discusses the negative impact that strongly hydrogen bonding monomers affect compliance and require that the macromonomers of Krampe (which Applicants note are insoluble) are added to maintain compliance and increase the liquid excipient that can be loaded into the pressure sensitive adhesive. See col. 6, lines 2-25.

Moreover, Garbe teaches away from water-solubility in a drug delivery device. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, . . . would be led in a direction divergent from the path that was taken by the applicant." *Tec Air, Inc. v. Denso Mfg. Mich. Inc.*, 192 F. 3d 1353, 1360 (Fed. Cir. 1999). Garbe specifies that the pressure sensitive sheet material contain a coating medium "not more than that amount which causes the product pressure sensitive adhesive sheet material to lose adhesion or leave substantial residue on the skin *when peeled from the skin*." Moreover, the liquid excipients used in the coating medium or described as "oily materials" capable of phase separating from the continuous phase when added in excessive amounts to form an "oily layer that reduces adhesion of an otherwise adhesive matrix." See col. 4, lines 47-49; col. 6, lines 58-65.

Because Garbe specifically teaches away using either a water-soluble / water-dispersible carrier or the water-soluble / water-dispersible adhesive, Garbe could not have provided one of ordinary skill in the art at the time the invention was made a reasonable expectation that water-solubility of the carrier, the adhesive, or both would effectively deliver an active agent to to a localized body surface. For at least these reasons, Garbe fails to disclose all the elements of the present invention to establish a *prima facie* case of obviousness.

Further, Garbe fails to disclose water-soluble polymer layers either alone or in combination with Scholz. The Examiner acknowledges that Garbe does not teach an active agent, and relies on Scholz for that disclosure. The Examiner concludes that it would have been obvious to one of skill in the art to modify the composition in Garbe based on the active agents provided in hydroalcoholic compositions as disclosed in Scholz.

Applicants submit that his conclusion can only be reached in hindsight using Applicants' disclosure. *In re Kotzab*, 208 F. 3d 1352 (Fed. Cir. 2000). Scholz discloses a hydroalcoholic composition for transdermal delivery of a pharmaceutical agent. Scholz fails to teach or disclose a water soluble/water dispersible carrier layer or a water soluble/water dispersible adhesive layer, and only discloses use of the hydroalcoholic composition with transdermal delivery devices known in the art. Moreover, Garbe teaches that the polymers be soluble in the "oily" liquid excipients. There is no teaching or suggestion in Scholz that the hydroalcoholic compositions disclosed therein would be soluble in the polymers in Garbe for coating on a substrate.

Thus, Applicants submit that Scholz fails to overcome the deficiencies in the teachings of Garbe. Accordingly, the combination of Garbe and Scholz fails to describe each and every element of claims 1 and 15 and, therefore, fails to establish a *prima facie* case of obviousness. Because claims 2-14 and 16-39 all depend from claim 1 and 15, Applicants submit that the combination of references also fails to establish a *prima facie* case of obviousness with respect to claims 2-14 and 16-39.

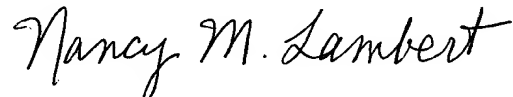
Therefore, rejection of claims 1-39 under 35 U.S.C. §103(a) is improper because (a) there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify Garbe to obtain the water-soluble or water –dispersible layers of the present invention; (b) there was no reasonable expectation of success; and (c) both references fail to teach or suggest all the claim limitations. For at least these reasons, Applicants respectfully maintain that the rejected claims, if properly construed, are patentable over both the cited references.

For all the above reasons, Garbe fails to disclose all the elements of the present invention to establish a *prima facie* case of obviousness. Applicants request that the rejections under 35 U.S.C. § 103(a) should be withdrawn.

**CONCLUSION**

In view of the foregoing, it is submitted that claims 1-39 are in condition for allowance in that they are patentable over the prior art cited by the Examiner. Accordingly, Applicants respectfully request that the Examiner's decision finally rejecting claims 1-39 of the subject application be reversed by the Board of Patent Appeals and Interferences.

Respectfully submitted,



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Dated: January 6, 2004

## **APPENDIX**

### **Rejected claims:**

1. (previously presented) A device for delivering at least one active agent to a localized body surface comprising:

    a substantially water-soluble or substantially water-dispersible carrier comprising at least one polymer and at least one plasticizer, and having a first surface and a second surface;

    a substantially water-soluble or substantially water-dispersible adhesive disposed on at least a portion of the first surface of the carrier, and having a carrier surface in contact with first surface of the carrier and an application surface opposed to the carrier surface; and

    at least one support layer releasably adhered to the application surface of the adhesive, the second surface of the carrier, or both.

2. (original) The device of claim 1 wherein the carrier comprises a polymeric film, a woven fabric, a knitted fabric, a nonwoven fabric, an open cell foam or a closed cell foam.

3. (original) The device of claim 1 wherein the at least one polymer is made from one or more substantially water-soluble or substantially water-dispersible monomers.

4. (original) The device of claim 1 wherein the at least one polymer comprises a polyvinyl alcohol, a polyvinyl pyrrolidone, a protein, a carbohydrate, an alginic acid, a polyethyleneimine, a polyoxyalkylene, a polyacrylate, a polymethacrylate, a polyacrylamide, a polymethacrylamide, a homopolymer of ethenically unsaturated monomers, or a copolymer comprising ethenically unsaturated monomers.

5. (original) The device of claim 4 wherein the protein is collagen, gelatin, any derivative thereof, or any combination of any of the foregoing.

6. (original) The device of claim 4 wherein the carbohydrate comprises arabinogalactan.



7. (original) The device of claim 1 wherein the at least one plasticizer comprises a monohydric alcohol, a polyhydric alcohol, polyethylene glycol, a polyether, a surfactant, an amide, a lactam, an amine, an amine salt,  $\alpha$ -tocopherol, or any mixture including any of any of the foregoing.

8. (original) The device of claim 7 wherein the monohydric alcohol is 3-methoxy-3-methyl-1-butanol, alkyl ether ethoxylate, alkyl ester ethoxylate, aryl ether ethoxylate, aryl ester ethoxylate, aralkyl ether ethoxylate, or aralkyl ester ethoxylate.

9. (original) The device of claim 7 wherein the polyhydric alcohol is glycerin, polyglycerol, alkyl polyglycoside, diethylene glycol, triethylene glycol, polyethylene glycol, a random copolymer of ethylene oxide and propylene oxide, a block copolymer of ethylene oxide and propylene oxide, propylene glycol, sorbitol, a sorbitol ester, butanediol, or an alkoxylated derivative of any of the foregoing.

10. (original) The device of claim 1 wherein the adhesive comprises a pressure sensitive adhesive.

11. (original) The device of claim 10 wherein the pressure sensitive adhesive comprises a mixture of:

i) at least one substantially water-soluble or substantially water-dispersible polymer, and

ii) at least one plasticizer in an amount sufficient to provide a desired degree of pressure sensitive tack.

12. (original) The device of claim 11 wherein the at least one substantially water-soluble or substantially water-dispersible polymer is made from at least one substantially water-soluble or substantially water-dispersible monomer.

13. (original) The device of claim 11 wherein the at least one substantially water-soluble or substantially water-dispersible polymer is poly(ethylene oxide), a

polysaccharide, a polysaccharide derivative, a homopolymer of ethenically unsaturated monomers, or a copolymer comprising ethenically unsaturated monomers.

14. (original) The device of claim 1 wherein the at least one support layer is paper, a polymeric film, a foil, or any combination of the foregoing.

15. (previously presented) A system for delivering at least one active agent to a localized body surface comprising:

a substantially water-soluble or substantially water-dispersible carrier comprising at least one polymer and at least one plasticizer, and having a first surface and a second surface;

a substantially water-soluble or substantially water-dispersible adhesive disposed on at least a portion of the first surface of the carrier, and having a carrier surface in contact with first surface of the carrier, and an application surface opposed to the carrier surface;

at least one active agent in association with the carrier, the adhesive, or both;  
and

at least one support layer releasably adhered to the application surface of the adhesive, the second surface of the carrier, or both.

16. (original) The system of claim 15 wherein the at least one active agent is effective for treatment of skin, hair, fingernails, toenails, teeth, or mucosal tissue.

17. (original) The system of claim 16 wherein the at least one active agent is a dye, a pigment, a bleaching agent, or a hair colorant.

18. (original) The system of claim 16 wherein the at least one active agent is a breath freshener, hydrogen peroxide, carbamide peroxide, sodium fluoride, sodium monophosphate, pyrophosphate, chlorhexidine gluconate, polyphosphate, triclosan, a flavorant, a fluoridating agent, a teeth whitening agent, a dental stain remover, a plaque remover, or a tartar remover.

19. (original) The system of claim 16 wherein the at least one active agent is a glitter, an ornamental design, a mask, an applique or a tattoo.

20. (original) The system of claim 16 wherein the at least one active agent is a fragrance, a perfume, an emollient, a humectant, a conditioner, a moisturizer, a surfactant, an herbal extract, a skin colorant, a color cosmetic, an emulsifier, a skin soothing agent, a skin tightening agent, an artificial tanning agent, a tanning accelerant, an anti-wrinkle agent, an exfolient, a sebum inhibiting agent, a sebum stimulator, a protease inhibitor, an anti-itch ingredient, an agent for inhibiting hair growth, an agent for accelerating hair growth, a hair remover, a skin sensate, a depilating agent or an astringent.

21. (original) The system of claim 16 wherein the at least one active agent is a sunscreen agent, an insect repellant, an antiperspirant or a deodorant.

22. (original) The system of claim 16 wherein the at least one active agent is a drug, a vitamin, a hormone, an antioxidant, an anti-inflammatory agent, a steroid, an antipruritic agent, an antifungal agent, an antibiotic, an antimicrobial agent, an antidandruff agent, an antiacne agent, a skin repair agent, a callus remover, a wart remover or a corn remover.

23. (original) The system of claim 15 wherein the at least one active agent is associated with the carrier.

24. (original) The system of claim 23 wherein the at least one active agent forms a coating on at least one surface of the carrier.

25. (original) The system of claim 23 wherein the at least one active agent is dissolved, suspended, or emulsified within the carrier.

26. (original) The system of claim 15 wherein the at least one active agent is associated with the adhesive.

27. (original) The system of claim 26 wherein the at least one active agent forms a coating on the application surface of the adhesive.

28. (original) The system of claim 26 wherein the at least one active agent is dissolved, suspended, or emulsified within the adhesive.

29. (original) The system of claim 15 wherein the carrier comprises a polymeric film, a woven fabric, a nonwoven fabric, an open cell foam or a closed cell foam.

30. (original) The system of claim 15 wherein the at least one polymer is made from one or more substantially water-soluble or substantially water-dispersible monomers.

31. (original) The system of claim 15 wherein the at least one polymer comprises a polyvinyl alcohol, a polyvinyl pyrrolidone, a protein, a carbohydrate, an alginic acid, a polyethyleneimine, a polyoxyalkylene, a polyacrylate, a polymethacrylate, a polyacrylamide, a polymethacrylamide, a homopolymer of ethenically unsaturated monomers, or a copolymer comprising ethenically unsaturated monomers.

32. (original) The system of claim 15 wherein the at least one plasticizer comprises a monohydric alcohol, a polyhydric alcohol, polyethylene glycol, a polyether, a surfactant, an amide, a lactam, an amine, an amine salt,  $\alpha$ -tocopherol, or any mixture including any of any of the foregoing.

33. (original) The system of claim 32 wherein the monohydric alcohol is 3-methoxy-3-methyl-1-butanol, an alkyl ether ethoxylate, an alkyl ester ethoxylate, an aryl ether ethoxylate, an aryl ester ethoxylate, an aralkyl ether ethoxylate, or an aralkyl ester ethoxylate.

34. (original) The system of claim 32 wherein the polyhydric alcohol is glycerin, a polyglycerol, an alkyl polyglycoside, diethylene glycol, triethylene glycol, a polyethylene glycol, a random copolymer of ethylene oxide and propylene oxide, a

block copolymer of ethylene oxide and propylene oxide, propylene glycol, sorbitol, a sorbitol ester, butanediol, or an alkoxylated derivative of any of the foregoing.

35. (original) The system of claim 15 wherein the adhesive comprises a pressure sensitive adhesive.

36. (original) The system of claim 35 wherein the pressure sensitive adhesive comprises a mixture of:

- i) at least one substantially water-soluble or substantially water-dispersible polymer, and
- ii) at least one plasticizer in an amount sufficient to provide a desired degree of pressure sensitive tack.

37. (original) The system of claim 36 wherein the at least one substantially water-soluble or substantially water-dispersible polymer is made from at least one substantially water-soluble or substantially water-dispersible monomer.

38. (original) The device of claim 36 wherein the at least one substantially water-soluble or substantially water-dispersible polymer comprises poly(ethylene oxide), a polysaccharide, a polysaccharide derivative, a homopolymer of ethenically unsaturated monomers, or a copolymer comprising ethenically unsaturated monomers.

39. (original) The system of claim 15 wherein the at least one support layer is paper, a polymeric film, a foil, or any combination of any of the foregoing.

40-50 (canceled)